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EXAMINER

TATE, CHRISTOPHER ROBIN

ART UNIT PAPER NUMBER

1654

DATE MAILED: 07/29/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/655,201

Applicant(s)

MAZAR ET AL.

Examiner

Christopher R. Tate

Art Unit

1654

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on Sep 3, 2003 (preliminary amendment).
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 15-32 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 15-32 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

### **DETAILED ACTION**

Claims 15-32 are presented for examination on the merits.

#### ***Claim Rejections - 35 USC § 101***

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 15-26 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. As drafted, claims 14-26 read upon a product of nature - e.g., although claim 1 recites a non-naturally occurring peptide, such a peptide could be found in nature in a form which is non-natural such as a mutant peptide or any other similar peptide found in nature having the claimed sequence, etc. It is suggested that claims 15 and 21 be amended to recite --An isolated peptide-- to overcome this rejection (see USC 112, second paragraph rejection below concerning the instant claim 15 phrasing).

#### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 15-26 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Art Unit: 1654

Claim 15 is rendered vague and indefinite by the phrase "A non-naturally occurring peptide, comprising" because it is unclear as to what "non-naturally occurring" is actually defining - e.g., is this attempting to define an isolated peptide, a peptide to which something else is attached/conjugated, a mutant peptide, or something else?

Claim 21 is rendered vague and indefinite by the phrase "A peptide comprising ...(SEQ ID NO: 2), wherein said peptide has 8 amino acid residues" because a peptide, *per se*, is made up of amino acids and the amino acid sequence of SEQ ID NO: 2 has a length of 8 amino acids. Accordingly, it is unclear by this overall phrase if Applicants are attempting to define a peptide which actually has more than 8 amino acids (via the term "comprising"), if they are attempting to define a peptide consisting of 8 amino acids (via the phrase "wherein said peptide has 8 amino acid residues"), or something else.

All other cited claims depend directly or indirectly from rejected claims and are, therefore, also rejected under USC 112, second paragraph for the reasons set forth above.

### ***Claim Rejections - 35 USC § 102/103***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

Art Unit: 1654

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 15-18, 20-24, and 26 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Blasi et al. (US 5,416,006).

Claims 15-18, 20-24, and 26 are also rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Kobayashi et al. (US 6,509,445 - please note the earliest priority date of this patent is January 8, 1996).

The claims are apparently drawn to a peptide comprising SEQ ID NO: 2.

Each of the cited references discloses short peptides (and compositions thereof) comprising instant SEQ ID NO:2, as well as labeled and/or therapeutic compound conjugates thereof. In addition, please note that any additional amino acids attached to the reference amino acids read upon a therapeutic agent conjugated thereto since the overall reference peptide sequences have therapeutic activity (see entire documents including, e.g., US '006 - col 18, line 39, col 22, Table 5, and col 23, SEQ ID NO: 8; US '554 - col 10, lines 29-35 and col 57, SEQ ID NO: 77). The instantly claimed functional properties would appear to be inherent to the peptides disclosed by the cited references. Consequently, the claimed peptide (and compositions thereof) appears to be anticipated by the reference. Please also note that the phrase "non-naturally occurring peptide" (e.g., claim 15) has not been afforded any patentable weight since a peptide is a peptide (which by definition is a series of two or more linked amino acids) no matter if it is naturally occurring, synthetically produced, or in some other way removed from nature.

Art Unit: 1654

In the alternative, even if the claimed peptide is not identical to the referenced peptides with regard to some unidentified characteristics, the differences between that which is disclosed and that which is claimed are considered to be so slight that the referenced peptides are likely to inherently possess the same characteristics of the claimed peptide particularly in view of the similar characteristics which they have been shown to share (including having 100% homology, each to the other, as well as having a similar overall amino acid length - e.g., 8 vs 9 vs 10 amino acids in length). Thus, the claimed peptide would have been obvious to those of ordinary skill in the art within the meaning of USC 103. If not expressly taught, it would also have been obvious one of ordinary skill in the art to label and/or attached a therapeutic agent to such a peptide, as these types of adjustments in conventional working conditions are deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan.

Accordingly, the claimed invention as a whole was at least *prima facie* obvious, if not anticipated by each of the cited references, especially in the absence of sufficient, clear, and convincing evidence to the contrary.

With respect to the above rejection, please note that the Patent and Trademark Office is not equipped to conduct experimentation in order to determine whether Applicants' peptide differs (e.g., functionally - including with respect to the instantly claimed functional properties) and, if so, to what extent, from those disclosed by the cited references. Therefore, with the showing of the references, the burden of establishing non-obviousness by objective evidence is shifted to the Applicants.

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 15-32 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-7 of U.S. Patent No. 5,994,309. Although the conflicting claims are not identical, they are not patentably distinct from each other because both are drawn to a peptide (and compositions thereof) comprising/consisting of the same amino acid sequence (SEQ ID NO: 2) including the peptide being capped with an N-terminal acetyl group and a C terminal amide group. In addition, the instant claims are encompassed by or, alternatively, encompass the claimed invention of US '309. It would also have been obvious one of ordinary skill in the art to label and/or attached a therapeutic agent to such a peptide, as these types of adjustments in conventional working conditions are deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan.

Art Unit: 1654

### **Conclusion**

No claim is allowed.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher R. Tate whose telephone number is (571) 272-0970. The examiner can normally be reached on Mon-Thur, 6:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campbell can be reached on (571) 272-0974. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Christopher R. Tate  
Primary Examiner  
Art Unit 1654